EXPLORATORY CENTERS (P20) FOR INTERDISCIPLINARY RESEARCH

RELEASE DATE: September 30, 2003

RFA Number: RFA-RR-04-002

Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATIONS:

National Institutes of Health (NIH) (http://www.nih.gov)

This RFA is developed as a roadmap initiative. All NIH Institutes and Centers participate in roadmap initiatives.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBERS: 93.389

LETTER OF INTENT RECEIPT DATE: January 30, 2004 **APPLICATION RECEIPT DATE:** February 24, 2004

THIS RFA CONTAINS THE FOLLOWING INFORMATION

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PURPOSE OF THIS RFA

In addition to the biological sciences, biomedical research encompasses a large number of scientific disciplines, including the behavioral, quantitative, engineering and computer sciences. Distinct disciplinary perspectives represent significant sources of strength to the overall research enterprise because each discipline has its own intellectual history, experimental and analytic approaches, and theoretical context that produce a unique way of thinking about a problem. Nevertheless, as scientific capabilities move

forward, increasingly complex questions arise, and these often require the convergence of perspectives from multiple disciplines. Over the years, the Institutes and Centers (ICs) of the National Institutes of Health (NIH) have developed many initiatives, mechanisms and programs to support multidisciplinary research--that is, research that brings together researchers from different disciplines to focus on a circumscribed problem.

It is becoming apparent that, in some cases, the collaborative nature of disciplines that characterizes multidisciplinary research is not sufficiently sustained to address, in a comprehensive and effective way, challenging problems in biomedical and behavioral research.

Rather, interdisciplinary research, which integrates several disciplinary approaches in a more sustained and systematic fashion, may be required to tackle these more complex problems. Integrating different disciplines in this way holds the promise of opening up currently unimagined scientific avenues of inquiry, and in the process, may form whole new disciplines. Historical examples include the development of genomics, which was formed from genetics, molecular biology, analytical chemistry, and informatics. Another example in which multiple disciplines have, in a less directed way, blended and evolved into a new discipline is neuroscience. Thirty years ago, students of the brain might have identified themselves as anatomists, physiologists, or psychobiologists, but today they would consider themselves neuroscientists.

Combining particular aspects of different disciplines to develop entirely new ways to approach biomedical and behavioral research problems is daunting in many ways. In recognition of the difficulty of establishing interdisciplinary research efforts, this Request for Applications (RFA) solicits applications for P20 planning grants that will support planning activities for groups of researchers to develop interdisciplinary research strategies to solve significant biomedical and/or behavioral research problems. Activities supported will include study design and, perhaps, pilot research to demonstrate the approach to be pursued. Whatever the approach, it must integrate aspects of multiple disciplines, which will be specified by the applicants. Planning activities are intended to lay the foundation and prepare investigators for submitting a subsequent application for more substantial and longer duration support through an Interdisciplinary Research Consortium. In recognition of the need to bring several disciplines together as equal partners, this RFA allows the research team to submit separate, but related applications that will be reviewed as a unit.

RESEARCH OBJECTIVES

This RFA invites applications for planning grants using the P20 (exploratory center) mechanism that will focus on developing new approaches to solving significant and complex biomedical problems, particularly those that have been resistant to more traditional approaches. These new approaches must hold the promise of leading to new research approaches to improving human health.

These planning grants are expected to identify a biomedically relevant problem, evaluate why previous approaches have not worked, justify why the proposed interdisciplinary approach will work, identify the planning approach, and propose a timeline. The planning approach could include holding workshops or conducting feasibility studies, but these are only examples of possible planning approaches.

It is expected that the outcome of these planning centers will demonstrate that the proposed interdisciplinary approach is likely to be successful. Success is defined as combining aspects of individual disciplines to provide a new approach to solving a problem that is likely to yield insights that could not have been achieved by an isolated laboratory or using a multi-disciplinary approach. The planning grant should request three years of funding.

In most cases, it is expected that the proposed centers will have leaders from more than one discipline. In order to recognize the intellectual input from scientists from more than one discipline and potentially from separate institutions, this RFA will allow contributing scientists to submit separate, but related, applications that address the same research problem. In addition to describing the research to be accomplished, these linked applications must address the nature of the collaboration. Whether applicants choose to submit one or multiple linked P20 applications, the development of interactions across disciplines must be specifically addressed. This innovative approach should allow each of the intellectual leaders to achieve appropriate credit for their contribution to this interdisciplinary project. This RFA also allows applications from single principal investigators who propose an interdisciplinary approach.

MECHANISM OF SUPPORT

This RFA will use NIH P20 award mechanism. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. This RFA is a one-time solicitation. The anticipated award date is September 2004.

This RFA uses just-in-time concepts. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2001/part_i_1.htm.

FUNDS AVAILABLE

The participating ICs intend to commit approximately \$9 million in FY 2004 to fund roughly fifteen new planning grants in response to this RFA. An applicant must request a project period of three years and a budget for direct costs of up to \$400,000 per year. The F&A costs (often called indirect costs) for any subcontracts will not count toward this \$400,000 cap. For linked applications, the total direct costs for all of the grants is limited to \$400,000; that is, the \$400,000 maximum budget will need to be distributed across the multiple, linked applications. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size also will vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this

RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Eligible agencies of the Federal government
- o Foreign institutions are not eligible to apply

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs or to partner with principal investigators from other institutions to develop a responsive application.

SPECIAL REQUIREMENTS

This RFA demonstrates the interest of NIH in supporting interdisciplinary research efforts as new pathways of discovery, but support by NIH is not sufficient for such research to prosper. More important is the commitment by research institutions to foster and accommodate interdisciplinary research.

Therefore, applicant organizations must describe their plans to facilitate interdisciplinary research as it relates to the P20 planning grant. Among the issues that should be addressed are: 1) how the institution will distribute credit for direct (and indirect) costs to reflect the contributions of different components, 2) how the institution will recognize the contributions of the research team beyond the Principal Investigator, and 3) how the institution attends to the careers of "interstitial" team members who play important roles in interdisciplinary research, but who are not tenure track or eligible/appropriate to be principal investigators on research grants. Applicant institutions are encouraged to describe how interdisciplinary research will be facilitated beyond these three issues.

This description of institutional commitment should be included as a letter from an appropriate representative of the applicant institution. It is likely that the appropriate institutional representative will have authority beyond a single department.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Greg Farber, Ph.D. Division of Biomedical Technology National Center for Research Resources 6701 Democracy Boulevard, Room 960 Bethesda, MD 20892-4874 Telephone: (301) 435-0778

FAX: (301) 480-3659 Email: gf48a@nih.gov

Michael F. Huerta, Ph.D. Associate Director, Scientific Technology and Research National Institute of Mental Health 6001 Executive Blvd., Room 7202 Bethesda, MD 20892-9645 Telephone: (301) 443-3563

FAX: (301) 443-4822 Email: mh38f@nih.gov

o Direct your questions about peer review issues to:

Sheryl Brining, Ph.D.
Director, Office of Review
National Center for Research Resources
6701 Democracy Blvd, Rm 1074
Bethesda MD 20892-4868
Telephone: (301) 435-0809

FAX: (301) 480-3660 Email: sb44k@nih.gov

o Direct your questions about financial or grants management matters to:

Mary Niemiec Office of Grants Management National Center for Research Resources 6701 Democracy Blvd, Rm 1046 Bethesda, MD 20892-4874 Telephone: (301) 435-0842

FAX: (301) 480-3777

Email: mn20z@nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

- o Descriptive title of the proposed research
- o Name, address, and telephone number of the Principal Investigator
- o Name, address, and telephone number of collaborating Principal Investigators if a linked application is submitted.
- o Names of other key personnel
- o Participating institutions
- o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Greg Farber, Ph.D.
Division of Biomedical Technology
National Center for Research Resources
6701 Democracy Boulevard, Room 960
Bethesda, MD 20892-4874
Telephone: (301) 435-0778

FAX: 301-480-3659 Email: gf48a@nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at http://www.dunandbradstreet.com/. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at

http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

SPECIFIC INSTRUCTIONS FOR ALL APPLICATIONS

Required information, in addition to that requested in the PHS 398 Form Instructions, is listed below

1) Timeline

A specific section labeled Timeline must be included following the Research Design and Methods section. The timeline should show the planned actions over the three-year period of the award. The timeline section must be contained within the 25-page limit.

2) Meeting

All awardees should plan to attend a meeting in the Washington, DC area in the second year of the award. Awardees will be expected to present their results at the meeting and will help NIH staff plan for future programs to support interdisciplinary research at NIH. The budget should contain support for travel for the project leaders for this meeting.

3) Management Plan

A plan should be presented for how the team will collaborate and how the efforts of the individual investigators will be coordinated. This concise management plan should be presented in a separate section following the Research Design and Methods section and must be contained within the 25-page limit.

4) Institutional Barriers to Interdisciplinary Research

The items mentioned in the Special Requirements section should be addressed in a letter from the appropriate institutional official. This letter should follow the Management Plan in the application.

5) Budget

The modular budget format should not be used.

SPECIFIC INSTRUCTIONS FOR SEPARATE APPLICATIONS FROM RESEARCH A TEAM (LINKED APPLICATIONS)

It is important that applicants who wish to submit linked applications announce their intentions clearly and early. Linked applications must mention the linkage in 4 separate areas of the application: the letter of intent, the cover letter included with the application, the title of the proposal, and in the abstract.

1) Letter of Intent

Linked applications should be clearly identified in letters of intent. Each Principal Investigator for the linked proposals should send a separate letter as detailed above. In the letter, the name and institution of the other members of the team should be identified clearly.

2) Cover Letter

To aid the Division of Receipt and Referral in making appropriate assignments, it is essential that the other members of a linked group be identified in the cover letter of the application. The cover letter should mention that this is a linked application and give the title(s), PI name(s), and originating institution(s) of application(s) that are linked.

3) Title

Linked applications must have identical titles followed by the phrase (number of number). An appropriate title would be "Plans for Interdisciplinary Studies of Obesity (1 of 2)".

4) Abstract

The fact that this is a linked application should be specified in the abstract of the application. The names and institutions of the other "linked" Principal Investigators should be in the abstract.

5) Budget

Linked applications can request, at most, \$400,000 in total direct costs for ALL awards (e.g., if two applications are linked, and if one requests \$250,000, the other linked application could only request up to \$150,000). The modular budget format should not be used.

6) Research Plan and Common Text

The PHS 398 form instructs applicants to divide the Research Plan section of the application into four parts (A-D) to answer the following questions:

- A) What do you intend to do?
- B) Why is the work important?
- C) What has already been done?
- D) How are you going to do the work?

For linked applications, it is expected that sections A, and B will be the same in each linked application. Section C may or may not have common text between linked applications. Section D should be different for each of the components of a linked application.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/labels.pdf.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center For Scientific Review National Institutes Of Health 6701 Rockledge Drive, Room 1040, MSC 7710 Bethesda, MD 20892-7710 Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application and five copies of the appendix material must be sent to:

Office of Review National Center For Research Resources 6701 Democracy Boulevard, 10th floor Bethesda, MD 20892-4874 Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received on or before the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to an RFA, it is to be prepared as a NEW application. That is, the application for the RFA must not include an Introduction describing the changes from the previous unfounded version of the application.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the (IC). Incomplete and/or nonresponsive applications will not be reviewed.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCRR in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

- o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
- o Receive a written critique
- o Receive a second level review by an appropriate National Advisory Council or Board.

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of bio-medical and behavioral systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The scientific review group will address and consider each of these criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

SIGNIFICANCE: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Do the applicants

acknowledge potential problem areas and consider alternative tactics? Are the appropriate disciplines adequately represented and well integrated to approach this complex research question?

INNOVATION: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

INVESTIGATORS: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigators and other researchers (if any)?

ENVIRONMENT: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, the following items will be considered in the determination of scientific and technical merit and in the determination of the priority score:

- 1) Is the proposed approach interdisciplinary? Are the appropriate disciplines included to provide a unified approach to the problem?
- 2) Does the proposed interdisciplinary approach have the potential to significantly change the way research on this topic is pursued?
- 3) Is there a plan in place to ensure that the collaboration runs smoothly? Does the management plan ensure that there will be sufficient coordination and collaboration among the members of the research team?
- 4) Will the proposed timeline allow the research team and NIH program staff to assess the impact of the anticipated interdisciplinary approach to solving a biomedical problem by the end of the award?
- 5) Will this interdisciplinary approach accomplish more than what would be accomplished by individuals working separately on the same problem, i.e. is the whole greater than the sum of the parts?

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL CONSIDERATIONS

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: January 30, 2004 Application Receipt Date: February 24, 2004

Peer Review Date: July 2004 Council Review: September 2004

Earliest Anticipated Start Date: September 2004

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

- o Scientific merit (as determined by peer review)
- o Availability of funds
- o Programmatic priorities.

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

DATA AND SAFETY MONITORING PLAN: Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to

the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women min/guidelines amended 10 2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide, in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110 guidance dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION:

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy/policy/htm

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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